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encompasses 50% or more of the locus of pain, and wherein the administration is is not at the locus of pain, thereby relieving the pain for at least one month. month.

24. The method of claim 23 wherein the patient has at least eleven loci of pain.

25. The method of claim 23 wherein the locus of pain and the peripheral location are located within a dermatome.

26. The method of claim 23 wherein the botulinum toxin is selected from the group consisting of botulinum neurotoxin types A, B, C, D, E, F, and G.

27. The method of claim 23 wherein the botulinum toxin is a botulinum toxin type A.

28. The method of claim 23 wherein the location of administration and the locus of pain have neuronal processes that are projected from the same spinal sensory nerve root.

29. The method of claim 23 wherein the botulinum toxin is administered with a needle.

30. The method of claim 23 wherein the botulinum toxin is administered by needleless injection.

31. A method for treating fibromyalgia, the method comprising the step of administering subcutaneously or intramuscularly a therapeutically effective amount of a botulinum toxin type A to a dermatome of a patient afflicted with fibromyalgia, wherein the dermatome encompasses 50% or more of a locus of pain which is at a fibromyalgia tender point, and wherein the local administration is not at the locus of pain, thereby relieving a fibromyalgia pain for at least one month.

32. A method for treating fibromyalgia pain, the method comprising the step of administering subcutaneously or intramuscularly a therapeutically effective amount of a botulinum toxin type A to a dermatome of a patient, wherein the patient has a locus of pain which is at a fibromyalgia tender point, wherein the dermatome encompasses 50% or more of the locus of pain, and wherein the administration is not at the locus of pain, thereby relieving the pain for at least one month.

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Sep 23, 2003

US-PAT-NO: 6623742

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TITLE: Methods for treating fibromyalgia

DATE-ISSUED: September 23, 2003

INVENTOR-INFORMATION:

| NAME | CITY | STATE | ZIP CODE | COUNTRY |
|-----------------|---------------------|-------|----------|---------|
| Voet; Martin A. | San Juan Capistrano | CA | | |

US-CL-CURRENT: 424/236.1; 424/247.1, 435/71.3, 514/12, 514/2, 530/344, 530/350

CLAIMS:

What is claimed is:

1. A method for treating fibromyalgia, the method comprising the step of administering subcutaneously or intramuscularly a therapeutically effective amount of a botulinum toxin to a peripheral location of a body of a patient afflicted with fibromyalgia, wherein the peripheral location is not a locus of pain, and wherein the locus of pain and the site of administration are located within a same dermatome, thereby relieving a fibromyalgia pain for at least one month.
2. The method of claim 1 wherein the peripheral location is in a head of the patient, and wherein the locus of pain is not in the head of the patient.
3. The method of claim 1 wherein the peripheral location is in a head of the patient, and wherein the locus of pain is at a fibromyalgia tender point.
4. The method of claim 1 wherein the peripheral location is in a cranial area or a facial area of the patient, and wherein the locus of pain is at a fibromyalgia tender point.
5. The method of claim 1 wherein the botulinum toxin is selected from the group consisting of botulinum toxin types A, B, C, D, E, F, and G.
6. The method of claim 1 wherein the botulinum toxin is a botulinum toxin type A.
7. The method of claim 1 wherein the location of peripheral administration and the locus of pain have neuronal processes that are projected from the same spinal sensory nerve root.
8. The method of claim 1 wherein the botulinum toxin is administered with a needle.
9. The method of claim 1 wherein the botulinum toxin is administered by

needleless injection.

10. A method for treating fibromyalgia pain, the method comprising the step of administering subcutaneously or intramuscularly a therapeutically effective amount of a botulinum toxin to a peripheral location of a body of a patient, wherein the patient has a locus of pain at a fibromyalgia tender point, and wherein the peripheral location is not at the locus of pain, and the locus of pain and the site of administration are located within a same dermatome, thereby relieving the pain for at least one month.

11. The method of claim 10 wherein the patient has at least eleven loci of pain.

12. The method of claim 10 wherein the botulinum toxin is selected from the group consisting of botulinum neurotoxin types A, B, C, D, E, F, and G.

13. The method of claim 10 wherein the botulinum toxin is a botulinum toxin type A.

14. The method of claim 10 wherein the location of peripheral administration and the locus of pain have neuronal processes that are projected from the same spinal sensory nerve root.

15. The method of claim 10 wherein the botulinum toxin is administered with a needle.

16. The method of claim 10 wherein the botulinum toxin is administered by needleless injection.

17. A method for treating fibromyalgia, the method comprising the step of administering subcutaneously or intramuscularly a therapeutically effective amount of a botulinum toxin to a dermatome of a patient afflicted with fibromyalgia, wherein the dermatome encompasses 50% or more of a locus of pain, wherein the administration is not at the locus of pain, thereby relieving a fibromyalgia pain for at least one month.

18. The method of claim 17 wherein the botulinum toxin is selected from the group consisting of botulinum toxin types A, B, C, D, E, F, and G.

19. The method of claim 17 wherein the botulinum toxin is a botulinum toxin type A.

20. The method of claim 17 wherein the location of administration and the locus of pain have neuronal processes that are projected from the same spinal sensory nerve root.

21. The method of claim 17 wherein the botulinum toxin is administered with a needle.

22. The method of claim 17 wherein the botulinum toxin is administered by needleless injection.

23. A method for treating fibromyalgia pain, the method comprising the step of administering subcutaneously or intramuscularly a therapeutically effective amount of a botulinum toxin to a dermatome of a patient, wherein the patient has a locus of pain at a fibromyalgia tender point, wherein the dermatome

encompasses 50% or more of the locus of pain, and wherein the administration is not at the locus of pain, thereby relieving the pain for at least one month. month.

24. The method of claim 23 wherein the patient has at least eleven loci of pain.

25. The method of claim 23 wherein the locus of pain and the peripheral location are located within a dermatome.

26. The method of claim 23 wherein the botulinum toxin is selected from the group consisting of botulinum neurotoxin types A, B, C, D, E, F, and G.

27. The method of claim 23 wherein the botulinum toxin is a botulinum toxin type A.

28. The method of claim 23 wherein the location of administration and the locus of pain have neuronal processes that are projected from the same spinal sensory nerve root.

29. The method of claim 23 wherein the botulinum toxin is administered with a needle.

30. The method of claim 23 wherein the botulinum toxin is administered by needleless injection.

31. A method for treating fibromyalgia, the method comprising the step of administering subcutaneously or intramuscularly a therapeutically effective amount of a botulinum toxin type A to a dermatome of a patient afflicted with fibromyalgia, wherein the dermatome encompasses 50% or more of a locus of pain which is at a fibromyalgia tender point, and wherein the local administration is not at the locus of pain, thereby relieving a fibromyalgia pain for at least one month.

32. A method for treating fibromyalgia pain, the method comprising the step of administering subcutaneously or intramuscularly a therapeutically effective amount of a botulinum toxin type A to a dermatome of a patient, wherein the patient has a locus of pain which is at a fibromyalgia tender point, wherein the dermatome encompasses 50% or more of the locus of pain, and wherein the administration is not at the locus of pain, thereby relieving the pain for at least one month.

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File: PGPB

Jul 1, 2004

PGPUB-DOCUMENT-NUMBER: 20040126397
PGPUB-FILING-TYPE: new
DOCUMENT-IDENTIFIER: US 20040126397 A1

TITLE: Use of the neurotoxic component of a botulinum toxin for treating various disorders and conditions and associated pain

PUBLICATION-DATE: July 1, 2004

INVENTOR-INFORMATION:

| NAME | CITY | STATE | COUNTRY | RULE-47 |
|----------------------|---------------------|-------|---------|---------|
| Aoki, Kei Roger | Coto De Caza | CA | US | |
| Grayston, Michael W. | Irvine | CA | US | |
| Carlson, Steven R. | San Mateo | CA | US | |
| Leon, Judith M. | San Juan Capistrano | CA | US | |

US-CL-CURRENT: 424/239.1

CLAIMS:

What is claimed is:

1. A method for treating strabismus, the method comprising the step of administering to a patient a therapeutically effective amount of a neurotoxic component of a botulinum toxin substantially free of a botulinum toxin complex protein.
2. The method of claim 1, wherein the botulinum toxin is selected from the group consisting of botulinum toxin types A, B, C, D, E, F and G.
3. The method of claim 1, wherein the neurotoxic component of the botulinum toxin has a molecular weight of about 150 kilodaltons.
4. The method of claim 1, wherein the botulinum toxin is a botulinum toxin type A.
5. A method for treating strabismus, the method comprising the step of administering to a patient a therapeutically effective amount of a neurotoxic component of a botulinum toxin type A substantially free of a botulinum toxin complex protein.
6. A method for treating blepharospasm, the method comprising the step of administering to a patient a therapeutically effective amount of a neurotoxic component of a botulinum toxin substantially free of a botulinum toxin complex protein.
7. The method of claim 6, wherein the botulinum toxin is selected from the group consisting of botulinum toxin types A, B, C, D, E, F and G.

8. The method of claim 6, wherein the neurotoxic component of the botulinum toxin has a molecular weight of about 150 kilodaltons.
9. The method of claim 6, wherein the botulinum toxin is a botulinum toxin type A.
10. A method for treating blepharospasm, the method comprising the step of administering to a patient a therapeutically effective amount of a neurotoxic component of a botulinum toxin type A substantially free of a botulinum toxin complex protein.
11. A method for treating cervical dystonia, the method comprising the step of administering to a patient a therapeutically effective amount of a neurotoxic component of a botulinum toxin substantially free of a botulinum toxin complex protein.
11. The method of claim 11, wherein the botulinum toxin is selected from the group consisting of botulinum toxin types A, B, C, D, E, F and G.
12. The method of claim 11, wherein the neurotoxic component of the botulinum toxin has a molecular weight of about 150 kilodaltons.
13. The method of claim 11, wherein the botulinum toxin is a botulinum toxin type A.
14. A method for treating cervical dystonia, the method comprising the step of administering to a patient a therapeutically effective amount of a neurotoxic component of a botulinum toxin type A substantially free of a botulinum toxin complex protein.
15. A method for treating neuromuscular disorders, the method comprising the step of administering to a patient a therapeutically effective amount of a neurotoxic component of a botulinum toxin substantially free of a botulinum toxin complex protein.
16. The method of claim 15, wherein the botulinum toxin is selected from the group consisting of botulinum toxin types A, B, C, D, E, F and G.
17. The method of claim 15, wherein the neurotoxic component of the botulinum toxin has a molecular weight of about 150 kilodaltons.
18. The method of claim 15, wherein the botulinum toxin is a botulinum toxin type A.
19. A method for treating a neuromuscular disorder, the method comprising the step of administering to a patient a therapeutically effective amount of a neurotoxic component of a botulinum toxin type A substantially free of a botulinum toxin complex protein.
20. A method for treating a cholinergic influenced secretion, the method comprising the step of administering to a patient a therapeutically effective amount of a neurotoxic component of a botulinum toxin substantially free of a botulinum toxin complex protein.
21. The method of claim 20, wherein the botulinum toxin is selected from the group consisting of botulinum toxin types A, B, C, D, E, F and G.

22. The method of claim 20, wherein the neurotoxic component of the botulinum toxin has a molecular weight of about 150 kilodaltons.
23. The method of claim 20, wherein the botulinum toxin is a botulinum toxin type A.
24. The method of claim 20, wherein the cholinergic influenced secretion is a sweat secretion.
25. A method for treating a cholinergic influenced secretion, the method comprising the step of administering to a patient a therapeutically effective amount of a neurotoxic component of a botulinum toxin type A substantially free of a botulinum toxin complex protein.
26. A method for treating a cholinergic influenced sweat secretion, the method comprising the step of administering to a patient a therapeutically effective amount of a neurotoxic component of a botulinum toxin type A substantially free of a botulinum toxin complex protein.
27. A method for treating a neuromuscular disorder or a cholinergic influenced secretion, the method comprising the step of administering to a patient a therapeutically effective amount of a neurotoxic component of a botulinum toxin substantially free of a botulinum toxin complex protein, wherein the neurotoxic component has a molecular weight of about 150 kilodaltons.

First Hit

L9: Entry 51 of 122

File: PGPB

Jan 17, 2002

PGPUB-DOCUMENT-NUMBER: 20020006905
PGPUB-FILING-TYPE: new
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TITLE: Use of botulinum toxins for treating various disorders and conditions and associated pain

PUBLICATION-DATE: January 17, 2002

INVENTOR-INFORMATION:

| NAME | CITY | STATE | COUNTRY | RULE-47 |
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| Grayston, Michael W. | Irvine | CA | US | |
| Carlson, Steven R. | Laguna Niguel | CA | US | |
| Leon, Judith M. | Laguna Niguel | CA | US | |

US-CL-CURRENT: 514/12

CLAIMS:

What is claimed is:

1. A method of treating cholinergic controlled secretions including excessive sweating, lacrimation and mucus secretion, said method comprising administering to the patient a therapeutically effective amount of Botulinum toxin type A in order to reduce the secretion.
2. The method according to claim 1 wherein the Botulinum toxin type A is administered to the patient's nerve plexus in an amount of between about 0.01 and about 50 units.
3. The method according to claim 1 wherein the Botulinum toxin type A is administered to the patient's ganglion in an amount of between about 0.01 and about 50 units.
4. The method according to claim 1 wherein the Botulinum toxin type A is administered to the patient's spinal cord in an amount of between about 0.01 and about 50 units.
5. The method according to claim 1 wherein the Botulinum toxin type A is administered to the patient's central nervous system in an amount of between about 0.01 and about 50 units.
6. A method for relieving pain associated with smooth muscle disorders, including spasms in the sphincters of the cardiovascular arteriole, gastrointestinal system, urinary, gall bladder and rectum, said method comprising administering to the patient a therapeutically effective amount of Botulinum toxin type A in order to relieve pain.

7. The method according to claim 6 wherein the Botulinum toxin type A is administered to the patient's pyloric valve in an amount between about 1 and about 50 units.
8. A method for treating smooth muscle disorders, including spasms in the sphincters of the cardiovascular arteriole, gastrointestinal system, urinary, gall bladder and rectum, said method comprising administering to the patient a therapeutically effective amount of Botulinum toxin type A in order to lessen the spasms.
9. The method according to claim 8 wherein the Botulinum toxin type A is administered to the patient's pyloric valve in an amount between about 1 and about 50 units.
10. A method for relieving pain associated with smooth muscle disorders, including spasms in the lower gastrointestinal muscles and rectum, said method comprising administering to the patient a therapeutically effective amount of Botulinum toxin type A in order to relieve pain.
11. The method according to claim 10 wherein the Botulinum toxin type A is administered to the patient's lower colon in an amount between about 0.01 and about 50 units.
12. A method for relieving pain associated with smooth muscle disorders, including spasms in the sphincters lower gastrointestinal muscles and rectum, said method comprising administering to the patient a therapeutically effective amount of Botulinum toxin type A in order to lessen the spasms.
13. The method according to claim 12 wherein the Botulinum toxin type A is administered to the patient's lower colon in an amount between about 0.01 and about 50 units.
14. A method for relieving pain associated with muscle spasms in conditions secondary to sports injuries, said method comprising administering to a patient a therapeutically effective amount of a Botulinum toxin of a type having short duration activity in order to relieve pain.
15. The method according to claim 14 wherein the Botulinum toxin comprises Botulinum toxin type F.
16. The method according to claim 15 wherein the therapeutic amount comprises a dose of between about 1 and about 10 units.
17. The method according to claim 16 wherein the muscle spasms occur in a patient's thigh and the Botulinum toxin is administered into the thigh
18. A method for relieving pain associated with contractions in arthritis, said method comprising administering to a patient a therapeutically effective amount of a Botulinum toxin in order to relieve pain.
19. A method for treating swallowing disorders, including spasms, said method comprising administering to the patient a therapeutically effective amount of Botulinum toxin type A.
20. A method for treating tension headache comprising administering to the patient a therapeutically effective amount of Botulinum toxin type A.

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L9: Entry 78 of 122

File: USPT

Oct 1, 2002

DOCUMENT-IDENTIFIER: US 6458365 B1
TITLE: Method for treating headache

Abstract Text (1):

A method and composition for treating a patient suffering from a disease, disorder or condition and associated pain include the administration to the patient of a therapeutically effective amount of a neurotoxin selected from a group consisting of of Botulinum toxin types A, B, C, D, E, F and G.

Assignee Name (1):Allergan, Inc.Detailed Description Text (57):

A male, age 65, with excessive unilateral sweating is treated by administering 0.01 to 50 units, of Botulinum toxin, depending upon degree of desired effect. The larger the dose, usually the greater spread and duration of effect. Small doses are used initially. Any serotype toxin alone or in combination could be used in this indication. The administration is to the gland nerve plexus, ganglion, spinal cord or central nervous system to be determined by the physician's knowledge of the anatomy and physiology of the target glands and secretory cells. In addition, the appropriate spinal cord level or brain area can be injected with the toxin (although (although this would cause many effects, including general weakness). Thus, the gland (if accessible) or the nerve plexus or ganglion are the targets of choice. Excessive sweating, tearing (lacrimation), mucus secretion or gastrointestinal secretions are positively influenced by the cholinergic nervous system. Sweating and tearing are under greater cholinergic control than mucus or gastric secretion and would respond better to toxin treatment. However, mucus and gastric secretions could be modulated through the cholinergic system. All symptoms would be reduced or eliminated with toxin therapy in about 1-7 days. Duration would be weeks to several months.

Detailed Description Text (71):

The Use of Botulinum Toxin Types A-G in the Treatment of Muscle Spasms and Control of Pain Associated with Muscle Spasms in Spasticity Conditions Secondary to Stroke, Traumatic Brain or Spinal Cord Injury

CLAIMS:

1. A method for treating tension headache comprising administering to a patient by intramuscular or subcutaneous injection a therapeutically effective amount of Botulinum toxin type A to a muscle of the head or upper neck of the patient, thereby thereby relieving pain of a headache within one to seven days, wherein the headache is associated with a muscle contraction.
2. A method for treating headache, the method comprising the step of administering by intramuscular or subcutaneous injection an effective amount of a botulinum toxin to a muscle of the head or upper neck of a patient, thereby relieving a pain of a headache within one to seven days, wherein the headache is associated with a muscle contraction.

3. The method of claim 2, wherein the botulinum toxin is administered in an amount of between 0.01 units and 500 units.
4. The method of claim 2, wherein the botulinum toxin is administered in an amount of between 1 unit and 300 units.
5. The method of claim 2, wherein the botulinum toxin is administered in an amount of between 0.01 units and 50 units.
6. The method of claim 2, wherein the botulinum toxin is selected from the group consisting of botulinum toxin types A, B, C, D, E, F and G.
7. The method of claim 2, wherein the botulinum toxin is administered to a human patient.
9. A method for relieving tension headache, the method comprising the step of intramuscular injection into a cholinergic influenced muscle of the head or upper neck of a human patient of a therapeutically effective amount of botulinum toxin in order to relieve a pain associated with a tension headache within one to seven days.
11. The method of claim 9, wherein the botulinum toxin is selected from the group consisting of botulinum toxin types A, B, C, D, E, F and G.
12. A method of treating tension headache comprising administration by intramuscular or subcutaneous injection of a therapeutically effective amount of a botulinum toxin to a patient, thereby relieving pain associated with a tension headache within seven days.
13. A method for treating headache, the method comprising the step of administering by intramuscular or subcutaneous injection an effective amount of a botulinum toxin type A to a muscle of the head or upper neck of a patient, thereby relieving a pain of a headache within one to seven days, wherein the headache is associated with a muscle contraction.
14. A method for relieving tension headache, the method comprising the step of intramuscular injection into a cholinergic influenced muscle of the head or upper neck of a human patient of a therapeutically effective amount of botulinum toxin type A in order to relieve a pain associated with a tension headache within one to seven days.

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Jul 23, 2002

1. A method for treating an injured muscle, the method comprising the step of local administration of a therapeutically effective amount of a botulinum toxin to an injured muscle, thereby treating the injured muscle by promoting healing of the injured muscle within six weeks after the local administration of the botulinum toxin.
2. The method of claim 1, wherein the botulinum toxin is intramuscularly injected.
3. The method of claim 1, wherein the botulinum toxin immobilizes the injured muscle.
4. The method of claim 1, wherein the botulinum toxin is effective to immobilize the the injured muscle during phase 1 and phase 2 of a repair process of the injured muscle.
5. The method of claim 1, wherein the botulinum toxin is effective to immobilize the the injured muscle during phase 1 of a repair process of the injured muscle.
6. The method of claim 1, wherein the botulinum toxin is selected from the group consisting of botulinum toxin type A, B, C.sub.1, D, E, F, and G.
7. The method of claim 1, wherein the botulinum toxin is a recombinantly made botulinum toxin.
9. The method of claim 1, wherein the botulinum toxin is botulinum toxin type A.
10. The method of claim 1, wherein the botulinum toxin is botulinum toxin type B.
11. A method for treating an injured muscle, the method comprising the step of local administration of a therapeutically effective amount of a botulinum toxin type A to an injured muscle, thereby treating the injured muscle by promoting healing of the injured muscle within six weeks after the local administration of the botulinum toxin type A.

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Merriam-Webster Online Dictionary

One entry found for **intrathecal**.

Thesaurus

Main Entry: **in·tra·the·cal** ◀▶

Pronunciation: - 't h E - k & l

Function: *adjective*

: introduced into or occurring in the space under the arachnoid membrane of the brain or spinal cord

- **in·tra·the·cal·ly** ◀▶ / - k (& -) l E / *adverb*

For **More Information on "intrathecal"** go to Britannica.com

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Pronunciation Symbols

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Intrathecal

<anatomy> Within a sheath, for example, cerebrospinal fluid that is contained within the dura mater. It also refers to drugs administered into the cerebrospinal fluid bathing the spinal cord and brain.

(30 Sep 1997)

Previous: [intrastromal](#), [intrasynovial](#), [intratarsal](#), [intratendinous bursa of elbow](#)

Next: [intrathecal chemotherapy](#), [intrathecal injection](#), [intrathoracic](#)

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First Hit Fwd Refs

L5: Entry 7 of 14

File: USPT

Sep 23, 2003

US-PAT-NO: 6623742

DOCUMENT-IDENTIFIER: US 6623742 B2

TITLE: Methods for treating fibromyalgia

DATE-ISSUED: September 23, 2003

INVENTOR-INFORMATION:

| NAME | CITY | STATE | ZIP CODE | COUNTRY |
|-----------------|---------------------|-------|----------|---------|
| Voet; Martin A. | San Juan Capistrano | CA | | |

US-CL-CURRENT: 424/236.1; 424/247.1, 435/71.3, 514/12, 514/2, 530/344, 530/350

CLAIMS:

What is claimed is:

1. A method for treating fibromyalgia, the method comprising the step of administering subcutaneously or intramuscularly a therapeutically effective amount of a botulinum toxin to a peripheral location of a body of a patient afflicted with fibromyalgia, wherein the peripheral location is not a locus of pain, and wherein the locus of pain and the site of administration are located within a same dermatome, thereby relieving a fibromyalgia pain for at least one month.
2. The method of claim 1 wherein the peripheral location is in a head of the patient, and wherein the locus of pain is not in the head of the patient.
3. The method of claim 1 wherein the peripheral location is in a head of the patient, and wherein the locus of pain is at a fibromyalgia tender point.
4. The method of claim 1 wherein the peripheral location is in a cranial area or a facial area of the patient, and wherein the locus of pain is at a fibromyalgia tender point.
5. The method of claim 1 wherein the botulinum toxin is selected from the group consisting of botulinum toxin types A, B, C, D, E, F, and G.
6. The method of claim 1 wherein the botulinum toxin is a botulinum toxin type A.
7. The method of claim 1 wherein the location of peripheral administration and the locus of pain have neuronal processes that are projected from the same spinal sensory nerve root.
8. The method of claim 1 wherein the botulinum toxin is administered with a needle.
9. The method of claim 1 wherein the botulinum toxin is administered by

needleless injection.

10. A method for treating fibromyalgia pain, the method comprising the step of administering subcutaneously or intramuscularly a therapeutically effective amount of a botulinum toxin to a peripheral location of a body of a patient, wherein the patient has a locus of pain at a fibromyalgia tender point, and wherein the peripheral location is not at the locus of pain, and the locus of pain and the site of administration are located within a same dermatome, thereby relieving the pain for at least one month.

11. The method of claim 10 wherein the patient has at least eleven loci of pain.

12. The method of claim 10 wherein the botulinum toxin is selected from the group consisting of botulinum neurotoxin types A, B, C, D, E, F, and G.

13. The method of claim 10 wherein the botulinum toxin is a botulinum toxin type A.

14. The method of claim 10 wherein the location of peripheral administration and the locus of pain have neuronal processes that are projected from the same spinal sensory nerve root.

15. The method of claim 10 wherein the botulinum toxin is administered with a needle.

16. The method of claim 10 wherein the botulinum toxin is administered by needleless injection.

17. A method for treating fibromyalgia, the method comprising the step of administering subcutaneously or intramuscularly a therapeutically effective amount of a botulinum toxin to a dermatome of a patient afflicted with fibromyalgia, wherein the dermatome encompasses 50% or more of a locus of pain, wherein the administration is not at the locus of pain, thereby relieving a fibromyalgia pain for at least one month.

18. The method of claim 17 wherein the botulinum toxin is selected from the group consisting of botulinum toxin types A, B, C, D, E, F, and G.

19. The method of claim 17 wherein the botulinum toxin is a botulinum toxin type A.

20. The method of claim 17 wherein the location of administration and the locus of pain have neuronal processes that are projected from the same spinal sensory nerve root.

21. The method of claim 17 wherein the botulinum toxin is administered with a needle.

22. The method of claim 17 wherein the botulinum toxin is administered by needleless injection.

23. A method for treating fibromyalgia pain, the method comprising the step of administering subcutaneously or intramuscularly a therapeutically effective amount of a botulinum toxin to a dermatome of a patient, wherein the patient has a locus of pain at a fibromyalgia tender point, wherein the dermatome

First Hit Fwd Refs

L9: Entry 70 of 122

File: USPT

Sep 23, 2003

US-PAT-NO: 6623742

DOCUMENT-IDENTIFIER: US 6623742 B2

TITLE: Methods for treating fibromyalgia

DATE-ISSUED: September 23, 2003

INVENTOR-INFORMATION:

| NAME | CITY | STATE | ZIP CODE | COUNTRY |
|-----------------|---------------------|-------|----------|---------|
| Voet; Martin A. | San Juan Capistrano | CA | | |

US-CL-CURRENT: 424/236.1; 424/247.1, 435/71.3, 514/12, 514/2, 530/344, 530/350

CLAIMS:

What is claimed is:

1. A method for treating fibromyalgia, the method comprising the step of administering subcutaneously or intramuscularly a therapeutically effective amount of a botulinum toxin to a peripheral location of a body of a patient afflicted with fibromyalgia, wherein the peripheral location is not a locus of pain, and wherein the locus of pain and the site of administration are located within a same dermatome, thereby relieving a fibromyalgia pain for at least one month.
2. The method of claim 1 wherein the peripheral location is in a head of the patient, and wherein the locus of pain is not in the head of the patient.
3. The method of claim 1 wherein the peripheral location is in a head of the patient, and wherein the locus of pain is at a fibromyalgia tender point.
4. The method of claim 1 wherein the peripheral location is in a cranial area or a facial area of the patient, and wherein the locus of pain is at a fibromyalgia tender point.
5. The method of claim 1 wherein the botulinum toxin is selected from the group consisting of botulinum toxin types A, B, C, D, E, F, and G.
6. The method of claim 1 wherein the botulinum toxin is a botulinum toxin type A.
7. The method of claim 1 wherein the location of peripheral administration and the locus of pain have neuronal processes that are projected from the same spinal sensory nerve root.
8. The method of claim 1 wherein the botulinum toxin is administered with a needle.
9. The method of claim 1 wherein the botulinum toxin is administered by

needleless injection.

10. A method for treating fibromyalgia pain, the method comprising the step of administering subcutaneously or intramuscularly a therapeutically effective amount of a botulinum toxin to a peripheral location of a body of a patient, wherein the patient has a locus of pain at a fibromyalgia tender point, and wherein the peripheral location is not at the locus of pain, and the locus of pain and the site of administration are located within a same dermatome, thereby relieving the pain for at least one month.

11. The method of claim 10 wherein the patient has at least eleven loci of pain.

12. The method of claim 10 wherein the botulinum toxin is selected from the group consisting of botulinum neurotoxin types A, B, C, D, E, F, and G.

13. The method of claim 10 wherein the botulinum toxin is a botulinum toxin type A.

14. The method of claim 10 wherein the location of peripheral administration and the locus of pain have neuronal processes that are projected from the same spinal sensory nerve root.

15. The method of claim 10 wherein the botulinum toxin is administered with a needle.

16. The method of claim 10 wherein the botulinum toxin is administered by needleless injection.

17. A method for treating fibromyalgia, the method comprising the step of administering subcutaneously or intramuscularly a therapeutically effective amount of a botulinum toxin to a dermatome of a patient afflicted with fibromyalgia, wherein the dermatome encompasses 50% or more of a locus of pain, wherein the administration is not at the locus of pain, thereby relieving a fibromyalgia pain for at least one month.

18. The method of claim 17 wherein the botulinum toxin is selected from the group consisting of botulinum toxin types A, B, C, D, E, F, and G.

19. The method of claim 17 wherein the botulinum toxin is a botulinum toxin type A.

20. The method of claim 17 wherein the location of administration and the locus of pain have neuronal processes that are projected from the same spinal sensory nerve root.

21. The method of claim 17 wherein the botulinum toxin is administered with a needle.

22. The method of claim 17 wherein the botulinum toxin is administered by needleless injection.

23. A method for treating fibromyalgia pain, the method comprising the step of administering subcutaneously or intramuscularly a therapeutically effective amount of a botulinum toxin to a dermatome of a patient, wherein the patient has a locus of pain at a fibromyalgia tender point, wherein the dermatome

encompasses 50% or more of the locus of pain, and wherein the administration is not at the locus of pain, thereby relieving the pain for at least one month.

24. The method of claim 23 wherein the patient has at least eleven loci of pain.

25. The method of claim 23 wherein the locus of pain and the peripheral location are located within a dermatome.

26. The method of claim 23 wherein the botulinum toxin is selected from the group consisting of botulinum neurotoxin types A, B, C, D, E, F, and G.

27. The method of claim 23 wherein the botulinum toxin is a botulinum toxin type A.

28. The method of claim 23 wherein the location of administration and the locus of pain have neuronal processes that are projected from the same spinal sensory nerve root.

29. The method of claim 23 wherein the botulinum toxin is administered with a needle.

30. The method of claim 23 wherein the botulinum toxin is administered by needleless injection.

31. A method for treating fibromyalgia, the method comprising the step of administering subcutaneously or intramuscularly a therapeutically effective amount of a botulinum toxin type A to a dermatome of a patient afflicted with fibromyalgia, wherein the dermatome encompasses 50% or more of a locus of pain which is at a fibromyalgia tender point, and wherein the local administration is not at the locus of pain, thereby relieving a fibromyalgia pain for at least one month.

32. A method for treating fibromyalgia pain, the method comprising the step of administering subcutaneously or intramuscularly a therapeutically effective amount of a botulinum toxin type A to a dermatome of a patient, wherein the patient has a locus of pain which is at a fibromyalgia tender point, wherein the dermatome encompasses 50% or more of the locus of pain, and wherein the administration is not at the locus of pain, thereby relieving the pain for at least one month.

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L5: Entry 1 of 14

File: PGPB

Apr 1, 2004

PGPUB-DOCUMENT-NUMBER: 20040062776

PGPUB-FILING-TYPE: new

DOCUMENT-IDENTIFIER: US 20040062776 A1

TITLE: Botulinum toxin therapy for fibromyalgia

PUBLICATION-DATE: April 1, 2004

INVENTOR-INFORMATION:

| NAME | CITY | STATE | COUNTRY | RULE-47 |
|-----------------|---------------------|-------|---------|---------|
| Voet, Martin A. | San Juan Capistrano | CA | US | |

US-CL-CURRENT: 424/239.1

CLAIMS:

I claim:

1. A method for treating fibromyalgia, the method comprising the step of administering a botulinum toxin to a patient afflicted with fibromyalgia.
2. The method of claim 1 wherein the botulinum toxin is selected from the group consisting of botulinum toxin types A, B, C, D, E, F and G.
3. The method of claim 1 wherein the botulinum toxin is a botulinum neurotoxin type A.
4. The method of claim 1 wherein the botulinum toxin is administered subcutaneously.
5. The method of claim 1 wherein the botulinum toxin is administered intramuscularly.
6. A method for treating a fibromyalgia pain, the method comprising the step of administering locally a therapeutically effective amount of a botulinum neurotoxin to a patient with a fibromyalgia pain, thereby treating the fibromyalgia pain.
7. The method of claim 6 wherein the botulinum neurotoxin is selected from the group consisting of botulinum neurotoxin types A, B, C, D, E, F and G.
8. The method of claim 6 wherein the botulinum neurotoxin is a botulinum neurotoxin type A.
9. The method of claim 6 wherein the botulinum neurotoxin is administered subcutaneously or intramuscularly.

10. A method for treating fibromyalgia, the method comprising the step of administering a botulinum toxin to a patient with fibromyalgia, the botulinum toxin administering being carried out at a first location which first location is anatomically distinct from and/or anatomically distant from a second location, at which second location the patient has a fibromyalgia pain which is alleviated by the administration of the botulinum toxin at the first location, thereby treating fibromyalgia.
11. The method of claim 10, wherein the first location is a peripheral location.
12. The method of claim 10, wherein the second location is a locus of pain.
13. The method of claim 10, wherein the administering step is carried out by subcutaneous or intramuscular administering of the botulinum toxin.
14. The method of claim 10, wherein the first location is the head or neck of the patient.

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L5: Entry 2 of 14

File: PGPB

Jan 29, 2004

PGPUB-DOCUMENT-NUMBER: 20040018213

PGPUB-FILING-TYPE: new

DOCUMENT-IDENTIFIER: US 20040018213 A1

TITLE: Pain treatment by peripheral administration of a neurotoxin

PUBLICATION-DATE: January 29, 2004

INVENTOR-INFORMATION:

| NAME | CITY | STATE | COUNTRY | RULE-47 |
|---------------------|---------------|-------|---------|---------|
| Aoki, Kei Roger | Coto de Caza | CA | US | |
| Cui, Minglei | Irvine | CA | US | |
| Jenkins, Stephen W. | Mission Viejo | CA | US | |

US-CL-CURRENT: 424/239.1

CLAIMS:

We claim:

1. A method for treating pain, the method comprising the step of peripheral administration of a neurotoxin to a mammal, wherein the pain treated is not associated with a muscle spasm.
2. The method of claim 1, wherein the neurotoxin comprises a neuronal binding moiety moiety which is substantially native to the neurotoxin.
3. The method of claim 1, wherein the neurotoxin is a botulinum toxin.
4. The method of claim 1, wherein the neurotoxin is a botulinum toxin elected from the group consisting of botulinum toxin types A, B, C.sub.1, D, E, F and G.
5. The method of claim 1, wherein the neurotoxin is botulinum toxin type A.
6. The method of claim 1, wherein the neurotoxin is a modified neurotoxin having at least one amino acid deleted, modified or replaced.
7. The method of claim 1, wherein the neurotoxin is made at least in part by recombinant process.
8. The method of claim 1, wherein the neurotoxin is administered in an amount between about 0.01 U/kg and about 35 U/kg.
9. The method of claim 1, wherein the pain is substantially alleviated for between about 1 month and about 6 months.

10. The method of claim 1, wherein the peripheral administration step is carried out out prior to an onset of a nociceptive event or syndrome experienced by the mammal.
11. The method of claim 1, wherein the peripheral administration is carried out subsequent to an onset of a nociceptive event experienced by the mammal.
12. A method for alleviating pain, the method comprising the step of peripheral administration of a botulinum toxin to a human patient, thereby alleviating pain, wherein the pain is not associated with a muscle disorder.
13. The method of claim 12, wherein the neurotoxin is a botulinum toxin selected from the group consisting of botulinum toxin types A, B, C.sub.1, D, E, F and G.
14. A method for treating a pain, the method comprising the step of peripheral administration of a neurotoxin to a mammal, wherein the neurotoxin is a polypeptide comprising: a) a first amino acid sequence region comprising a wild type neuronal binding moiety, substantially completely derived from a neurotoxin selected from a group consisting botulinum toxin types A, B, C.sub.1, D, E, F, G and mixtures thereof; b) a second amino acid sequence region effective to translocate the polypeptide or a part thereof across an endosome membrane; and c) a third amino acid sequence region having therapeutic activity when released into a cytoplasm of a target cell, wherein the pain is not associated with a muscle spasm.
15. The method of claim 14, wherein the first amino acid sequence region of the polypeptide comprises a carboxyl terminal of a heavy chain derived from the neurotoxin.
16. The method of claim 14, wherein the neurotoxin is botulinum toxin type A.
17. The method of claim 14, wherein the second amino acid sequence region of the polypeptide comprises an amine terminal of a heavy chain derived from a neurotoxin selected from a group consisting of botulinum toxin types A, B, C.sub.1, D, E, F, G and mixtures thereof.
18. The method of claim 14, wherein the second amino acid sequence region of the polypeptide comprises an amine terminal of a toxin heavy chain derived from botulinum toxin type A.
19. The method of claim 14, wherein the third amino acid sequence region of the polypeptide comprises a toxin light chain derived from a neurotoxin selected from a group consisting of beratti toxin; butyricum toxin; tetani toxin; botulinum toxin types A, B, C.sub.1, D, E, F, G and mixtures thereof.
20. The method of claim 14, wherein the third amino acid sequence region of the polypeptide comprises a toxin light chain derived from botulinum toxin type A.
21. A method for improving patient function, the method comprising the step of peripheral administration of a botulinum toxin to a patient experiencing a non-muscle disorder related pain, thereby improving patient function as determined by improvement in one or more of the factors of reduced pain, reduced time spent in bed, improve hearing, increased ambulation, healthier attitude and a more varied lifestyle.
22. A method for treating post-operative pain, the method comprising the step of peripheral administration of an effective amount of a botulinum toxin before, during or immediately after a surgical procedure, thereby alleviating a post-operative pain, wherein the surgical procedure is not carried out to treat a muscle

spasm.

23 A method for treating a visceral pain the method comprising the step of non-systemic, local administration of an effective amount of a botulinum toxin, thereby alleviating a visceral pain.

24. A method for treating pain, the method comprising the step of peripheral administration of a neurotoxin to a mammal, wherein the pain is not substantially due to a muscle spasm.

25. The method of claim 24, wherein, the neurotoxin is a botulinum toxin.

26. The method of claim 24, wherein the pain is not secondary to a muscle spasm.

27. The method of claim 24, wherein the peripheral administration is by subcutaneous administration of the neurotoxin.

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L5: Entry 3 of 14

File: PGPB

Jan 29, 2004

PGPUB-DOCUMENT-NUMBER: 20040018212

PGPUB-FILING-TYPE: new

DOCUMENT-IDENTIFIER: US 20040018212 A1

TITLE: Joint pain treatment by peripheral administration of a neurotoxin

PUBLICATION-DATE: January 29, 2004

INVENTOR-INFORMATION:

| NAME | CITY | STATE | COUNTRY | RULE-47 |
|---------------------|---------------|-------|---------|---------|
| Aoki, Kei Roger | Coto de Caza | CA | US | |
| Cui, Minglei | Irvine | CA | US | |
| Jenkins, Stephen W. | Mission Viejo | CA | US | |

US-CL-CURRENT: 424/239.1

CLAIMS:

We claim:

1. A method for treating pain, the method comprising the step of peripheral administration of a neurotoxin to a mammal, wherein the pain treated is not associated with a muscle spasm.
2. The method of claim 1, wherein the neurotoxin comprises a neuronal binding moiety moiety which is substantially native to the neurotoxin.
3. The method of claim 1, wherein the neurotoxin is a botulinum toxin.
4. The method of claim 1, wherein the neurotoxin is a botulinum toxin elected from the group consisting of botulinum toxin types A, B, C.sub.1, D, E, F and G.
5. The method of claim 1, wherein the neurotoxin is botulinum toxin type A.
6. The method of claim 1, wherein the neurotoxin is a modified neurotoxin having at least one amino acid deleted, modified or replaced.
7. The method of claim 1, wherein the neurotoxin is made at least in part by a recombinant process.
8. The method of claim 1, wherein the neurotoxin is administered in an amount between about 0.01 U/kg and about 35 U/kg.
9. The method of claim 1, wherein the pain is substantially alleviated for between about 1 month and about 6 months.

10. The method of claim 1, wherein the peripheral administration step is carried out out prior to an onset of a nociceptive event or syndrome experienced by the mammal.
11. The method of claim 1, wherein the peripheral administration is carried out subsequent to an onset of a nociceptive event experienced by the mammal.
12. A method for alleviating pain, the method comprising the step of peripheral administration of a botulinum toxin to a human patient, thereby alleviating pain, wherein the pain is not associated with a muscle disorder.
13. The method of claim 12, wherein the neurotoxin is a botulinum toxin selected from the group consisting of botulinum toxin types A, B, C.sub.1, D, E, F and G.
14. A method for treating a pain, the method comprising the step of periph ral administration of a neurotoxin to a mammal, wherein the neurotoxin is a polypeptide comprising: a) a first amino acid sequence region comprising a wild type neuronal binding moiety, substantially completely derived from a neurotoxin selected from a group consisting botulinum toxin types A, B, C.sub.1, D, E, F, G and mixtures thereof; b) a second amino acid sequence region effective to translocate th polypeptide or a part thereof across an endosome membrane; and c) a third amino acid sequence region having therapeutic activity when released into a cytoplasm of a target cell, wherein the pain is not associated with a muscle spasm.
15. The method of claim 14, wherein the first amino acid sequence region of the polypeptide comprises a carboxyl terminal of a heavy chain derived from the neurotoxin.
16. The method of claim 14, wherein the neurotoxin is botulinum toxin type A.
17. The method of claim 14, wherein the second amino acid sequence region of the polypeptide comprises an amine terminal of a heavy chain derived from a neurotoxin selected from a group consisting of botulinum toxin types A, B, C.sub.1, D, E, F, G and mixtures thereof.
18. The method of claim 14, wherein the second amino acid sequence region of the polypeptide comprises an amine terminal of a toxin heavy chain derived from botulinum toxin type A.
19. The method of claim 14, wherein the third amino acid sequence region of the polypeptide comprises a toxin light chain derived from a neurotoxin selected from a group consisting of beratti toxin; butyricum toxin; tetani toxin; botulinum toxin types A, B, C.sub.1, D, E, F, G and mixtures thereof.
20. The method of claim 14, wherein the third amino acid sequence region of the polypeptide comprises a toxin light chain derived from botulinum toxin type A.
21. A method for improving patient function, the method comprising the step of peripheral administration of a botulinum toxin to a patient experiencing a non-muscle disorder related pain, thereby improving patient function as determined by improv ment in one or more of the factors of reduced pain, reduced time spent in bed, improve hearing, increased ambulation, healthier attitude and a more varied lifestyle.
22. A method for treating post-operative pain, the method comprising the st p of peripheral administration of an effective amount of a botulinum toxin before, during or immediately after a surgical procedure, thereby alleviating a post-operative pain, wherein the surgical procedure is not carried out to treat a muscle

spasm.

23. A method for treating a visceral pain the method comprising the step of non-systemic, local administration of an effective amount of a botulinum toxin, thereby alleviating a visceral pain.

24. A method for treating pain, the method comprising the step of peripheral administration of a neurotoxin to a mammal, wherein the pain is not substantially due to a muscle spasm.

25. The method of claim 24, wherein, the neurotoxin is a botulinum toxin.

26. The method of claim 24, wherein the pain is not secondary to a muscle spasm.

27. The method of claim 24, wherein the peripheral administration is by subcutaneous administration of the neurotoxin.

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DATE: Tuesday, July 06, 2004

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| | | <i>DB=PGPB,USPT,USOC,EPAB,JPAB,DWPI,TDBD; PLUR=YES; OP=AND</i> | |
| <input type="checkbox"/> | L1 | schizophren\$ | 15305 |
| <input type="checkbox"/> | L2 | L1 and (donovan.in. or allergan.asn.) | 3 |
| <input type="checkbox"/> | L3 | (donovan.in. or allergan.asn.) | 5142 |
| <input type="checkbox"/> | L4 | L3 and peripheral.ti,ab,clm. | 135 |
| <input type="checkbox"/> | L5 | L4 and (botulinum or botulism or botox or neurotoxin or neuro-toxin or toxin or clostrid\$) | 14 |

END OF SEARCH HISTORY

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-
- ☐ 1. [20040062776](#). 18 Sep 03. 01 Apr 04. Botulinum toxin therapy for fibromyalgia. Voet, Martin A.. 424/239.1; A61K039/08.
-
- ☐ 2. [20040018213](#). 29 Jul 03. 29 Jan 04. Pain treatment by peripheral administration of a neurotoxin. Aoki, Kei Roger, et al. 424/239.1; A61K039/08.
-
- ☐ 3. [20040018212](#). 29 Jul 03. 29 Jan 04. Joint pain treatment by peripheral administration of a neurotoxin. Aoki, Kei Roger, et al. 424/239.1; A61K039/08.
-
- ☐ 4. [20030054975](#). 17 Sep 01. 20 Mar 03. Methods for treating fibromyalgia. Voet, Martin A.. 514/2; A61K038/16.
-
- ☐ 5. [20020176872](#). 18 Jul 02. 28 Nov 02. Pain treatment by peripheral administration of a neurotoxin. Aoki, Kei Roger, et al. 424/247.1; A61K039/08.
-
- ☐ 6. [20020028216](#). 04 Oct 01. 07 Mar 02. Botulinum toxin implant. Donovan, Stephen. 424/236.1; A61K039/02.
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- ☐ 7. [6623742](#). 17 Sep 01; 23 Sep 03. Methods for treating fibromyalgia. Voet; Martin A.. 424/236.1; 424/247.1 435/71.3 514/12 514/2 530/344 530/350. A61K039/08 C07K014/33.
-
- ☐ 8. [6506399](#). 04 Oct 01; 14 Jan 03. Biodegradable botulinum toxin implant. Donovan; Stephen. 424/423; 424/184.1 424/236.1 424/422 424/426. A61K039/02 A61K039/00.
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- ☐ 9. [6312708](#). 21 Jul 00; 06 Nov 01. Botulinum toxin implant. Donovan; Stephen. 424/423; 424/184.1 424/236.1 424/422 424/426. A61K039/02 A61K039/00.
-
- ☐ 10. [WO2003099289A](#). Alleviation of pain e.g. neuropathic pain, visceral pain, post-operative pain, inflammatory pain, arthritic pain involves use of a composition comprising alpha-adrenergic agonist and a composition comprising selective alpha-2A antagonist. DONELLO, J E, et al. A61K031/137 A61K031/4164 A61K031/4166 A61K031/4168 A61K031/4178 A61K031/498 A61K031/538 A61P029/00.
-
- ☐ 11. [US20030054975A](#). Treatment of pain associated with fibromyalgia involves locally administering Clostridial neurotoxin to peripheral location of patient's body afflicted with fibromyalgia, where the location is not locus of pain. VOET, M A. A61K038/16 A61K039/08 C07K014/33.
-
- ☐ 12. [US20030027752A](#). Novel modified neurotoxin with a structural modification that alters biological persistence or activity of the modified neurotoxin relative to the unmodified neurotoxin, for treating tremors, bruxism and dysphagia. AOKI, K R, et al. A61K038/17 C07K014/435.
-
- ☐ 13. [WO 200208268A](#). Novel modified neurotoxin comprising structural modification which alters the biological persistence and/or biological activity of a neurotoxin, useful for treating neuromuscular or autonomic disorder, or pain. AOKI, K R, et al. A61K038/16 A61P021/00 A61P029/02 A61P037/00 C07K014/33.
-

☐ 14. US 6464986B. Treating a non-spasm caused pain involves peripheral administration of a neurotoxin to mammal. AOKI, K R, et al. A61K038/00 A61K038/16 A61K038/48 A61K039/02 A61K039/08 A61K045/00 A61P025/02 A61P029/02.

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| Terms | Documents |
|---|-----------|
| L4 and (botulinum or botulism or botox or neurotoxin or neuro-toxin or toxin or clostrid\$) | 14 |

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L5: Entry 1 of 14

File: PGPB

Apr 1, 2004

PGPUB-DOCUMENT-NUMBER: 20040062776
PGPUB-FILING-TYPE: new
DOCUMENT-IDENTIFIER: US 20040062776 A1

TITLE: Botulinum toxin therapy for fibromyalgia

PUBLICATION-DATE: April 1, 2004

INVENTOR-INFORMATION:

| NAME | CITY | STATE | COUNTRY | RULE-47 |
|-----------------|---------------------|-------|---------|---------|
| Voet, Martin A. | San Juan Capistrano | CA | US | |

ASSIGNEE-INFORMATION:

| NAME | CITY | STATE | COUNTRY | TYPE CODE |
|-----------------------|------|-------|---------|-----------|
| <u>Allergan, Inc.</u> | | | | 02 |

APPL-NO: 10/ 666408 [PALM]
DATE FILED: September 18, 2003

RELATED-US-APPL-DATA:

Application 10/666408 is a continuation-in-part-of US application 09/954610, filed September 17, 2001, US Patent No. 6623742

INT-CL: [07] A61 K 39/08

US-CL-PUBLISHED: 424/239.1

US-CL-CURRENT: 424/239.1

REPRESENTATIVE-FIGURES: NONE

ABSTRACT:

Methods for treating fibromyalgia by administering a therapeutically effective amount of a botulinum toxin to a patient with fibromyalgia.

CROSS REFERENCE

[0001] This application is a continuation in part of U.S. patent application Ser. No. 09/954,610, filed Sep. 17, 2001.

First Hit

L5: Entry 1 of 14

File: PGPB

Apr 1, 2004

PGPUB-DOCUMENT-NUMBER: 20040062776
PGPUB-FILING-TYPE: new
DOCUMENT-IDENTIFIER: US 20040062776 A1

TITLE: Botulinum toxin therapy for fibromyalgia

PUBLICATION-DATE: April 1, 2004

INVENTOR-INFORMATION:

| NAME | CITY | STATE | COUNTRY | RULE-47 |
|-----------------|---------------------|-------|---------|---------|
| Voet, Martin A. | San Juan Capistrano | CA | US | |

US-CL-CURRENT: 424/239.1

CLAIMS:

I claim:

1. A method for treating fibromyalgia, the method comprising the step of administering a botulinum toxin to a patient afflicted with fibromyalgia.
2. The method of claim 1 wherein the botulinum toxin is selected from the group consisting of botulinum toxin types A, B, C, D, E, F and G.
3. The method of claim 1 wherein the botulinum toxin is a botulinum neurotoxin type A.
4. The method of claim 1 wherein the botulinum toxin is administered subcutaneously.
5. The method of claim 1 wherein the botulinum toxin is administered intramuscularly.
6. A method for treating a fibromyalgia pain, the method comprising the step of administering locally a therapeutically effective amount of a botulinum neurotoxin to a patient with a fibromyalgia pain, thereby treating the fibromyalgia pain.
7. The method of claim 6 wherein the botulinum neurotoxin is selected from the group consisting of botulinum neurotoxin types A, B, C, D, E, F and G.
8. The method of claim 6 wherein the botulinum neurotoxin is a botulinum neurotoxin type A.
9. The method of claim 6 wherein the botulinum neurotoxin is administered subcutaneously or intramuscularly.
10. A method for treating fibromyalgia, the method comprising the step of administering a botulinum toxin to a patient with fibromyalgia, the botulinum toxin

administering being carried out at a first location which first location is anatomically distinct from and/or anatomically distant from a second location, at which second location the patient has a fibromyalgia pain which is alleviated by the administration of the botulinum toxin at the first location, thereby treating fibromyalgia.

11. The method of claim 10, wherein the first location is a peripheral location.

12. The method of claim 10, wherein the second location is a locus of pain.

13. The method of claim 10, wherein the administering step is carried out by subcutaneous or intramuscular administering of the botulinum toxin.

14. The method of claim 10, wherein the first location is the head or neck of the patient.

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☐ 1. Document ID: US 20030211121 A1

Using default format because multiple data bases are involved.

L2: Entry 1 of 3

File: PGPB

Nov 13, 2003

PGPUB-DOCUMENT-NUMBER: 20030211121

PGPUB-FILING-TYPE: new

DOCUMENT-IDENTIFIER: US 20030211121 A1

TITLE: Therapeutic treatments for neuropsychiatric disorders

PUBLICATION-DATE: November 13, 2003

INVENTOR-INFORMATION:

| | | | | |
|------------------|------------------|-------|---------|---------|
| NAME | CITY | STATE | COUNTRY | RULE-47 |
| Donovan, Stephen | Capistrano Beach | CA | US | |

US-CL-CURRENT: 424/247.1

| | | | | | | | | | | | | |
|------|-------|----------|-------|--------|----------------|------|-----------|-----------|-------------|--------|------|--------|
| Full | Title | Citation | Front | Review | Classification | Date | Reference | Sequences | Attachments | Claims | KWIC | Draw D |
|------|-------|----------|-------|--------|----------------|------|-----------|-----------|-------------|--------|------|--------|

☐ 2. Document ID: US 6306403 B1

L2: Entry 2 of 3

File: USPT

Oct 23, 2001

DOCUMENT-IDENTIFIER: US 6306403 B1

TITLE: Method for treating parkinson's disease with a botulinum toxin

INVENTOR (1):

Donovan; Stephen

Assignee Name (1):

Allergan Sales, Inc.

Other Reference Publication (21):

Hoffman, Ralph E., et al., Transcranial magnetic stimulation and auditory hallucinations in schizophrenia; The Lancet vol. 355, Mar. 25, 2000, 1073-1075.

| | | | | | | | | | | | | |
|------|-------|----------|-------|--------|----------------|------|-----------|-----------|-------------|--------|------|--------|
| Full | Title | Citation | Front | Review | Classification | Date | Reference | Sequences | Attachments | Claims | KWIC | Draw D |
|------|-------|----------|-------|--------|----------------|------|-----------|-----------|-------------|--------|------|--------|

☐ 3. Document ID: WO 2003094955 A1, US 20030211121 A1

L2: Entry 3 of 3

File: DWPI

Nov 20, 2003

DERWENT-ACC-NO: 2003-901566

DERWENT-WEEK: 200403

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TITLE: Treating a neuropsychiatric disorder, e.g. schizophrenia, Alzheimer's disease, mania or anxiety, comprises administering intracranially a clostridial neurotoxin or a botulinum toxin to a patient

INVENTOR: DONOVAN, S

PRIORITY-DATA: 2002US-0143078 (May 10, 2002)

PATENT-FAMILY:

| PUB-NO | PUB-DATE | LANGUAGE | PAGES | MAIN-IPC |
|-------------------|-------------------|----------|-------|------------|
| WO 2003094955 A1 | November 20, 2003 | E | 000 | A61K038/48 |
| US 20030211121 A1 | November 13, 2003 | | 015 | A61K039/08 |

INT-CL (IPC): A61 K 38/48; A61 K 39/08; A61 P 25/18; A61 P 25/22; A61 P 25/28

| | | | | | | | | | | | | |
|------|-------|----------|-------|--------|----------------|------|-----------|-----------|-----------|--------|------|--------|
| Full | Title | Citation | Front | Review | Classification | Date | Reference | Sequences | Abstracts | Claims | KWIC | Draw D |
|------|-------|----------|-------|--------|----------------|------|-----------|-----------|-----------|--------|------|--------|

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| L1 and (donovan.in. or allergan.asn.) | 3 |

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File: PGPB

Jan 29, 2004

PGPUB-DOCUMENT-NUMBER: 20040018213
PGPUB-FILING-TYPE: new
DOCUMENT-IDENTIFIER: US 20040018213 A1

TITLE: Pain treatment by peripheral administration of a neurotoxin

PUBLICATION-DATE: January 29, 2004

INVENTOR- INFORMATION:

| NAME | CITY | STATE | COUNTRY | RULE-47 |
|---------------------|---------------|-------|---------|---------|
| Aoki, Kei Roger | Coto de Caza | CA | US | |
| Cui, Minglei | Irvine | CA | US | |
| Jenkins, Stephen W. | Mission Viejo | CA | US | |

US-CL-CURRENT: 424/239.1

CLAIMS:

We claim:

1. A method for treating pain, the method comprising the step of peripheral administration of a neurotoxin to a mammal, wherein the pain treated is not associated with a muscle spasm.
2. The method of claim 1, wherein the neurotoxin comprises a neuronal binding moiety moiety which is substantially native to the neurotoxin.
3. The method of claim 1, wherein the neurotoxin is a botulinum toxin.
4. The method of claim 1, wherein the neurotoxin is a botulinum toxin elected from the group consisting of botulinum toxin types A, B, C.sub.1, D, E, F and G.
5. The method of claim 1, wherein the neurotoxin is botulinum toxin type A.
6. The method of claim 1, wherein the neurotoxin is a modified neurotoxin having at least one amino acid deleted, modified or replaced.
7. The method of claim 1, wherein the neurotoxin is made at least in part by recombinant process.
8. The method of claim 1, wherein the neurotoxin is administered in an amount between about 0.01 U/kg and about 35 U/kg.
9. The method of claim 1, wherein the pain is substantially alleviated for between about 1 month and about 6 months.
10. The method of claim 1, wherein the peripheral administration step is carried out out prior to an onset of a nociceptive event or syndrome experienced by the mammal.

11. The method of claim 1, wherein the peripheral administration is carried out subsequent to an onset of a nociceptive event experienced by the mammal.

12. A method for alleviating pain, the method comprising the step of peripheral administration of a botulinum toxin to a human patient, thereby alleviating pain, wherein the pain is not associated with a muscle disorder.

13. The method of claim 12, wherein the neurotoxin is a botulinum toxin selected from the group consisting of botulinum toxin types A, B, C.sub.1, D, E, F and G.

14. A method for treating a pain, the method comprising the step of peripheral administration of a neurotoxin to a mammal, wherein the neurotoxin is a polypeptide comprising: a) a first amino acid sequence region comprising a wild type neuronal binding moiety, substantially completely derived from a neurotoxin selected from a group consisting botulinum toxin types A, B, C.sub.1, D, E, F, G and mixtures thereof; b) a second amino acid sequence region effective to translocate the polypeptide or a part thereof across an endosome membrane; and c) a third amino acid sequence region having therapeutic activity when released into a cytoplasm of a target cell, wherein the pain is not associated with a muscle spasm.

15. The method of claim 14, wherein the first amino acid sequence region of the polypeptide comprises a carboxyl terminal of a heavy chain derived from the neurotoxin.

16. The method of claim 14, wherein the neurotoxin is botulinum toxin type A.

17. The method of claim 14, wherein the second amino acid sequence region of the polypeptide comprises an amine terminal of a heavy chain derived from a neurotoxin selected from a group consisting of botulinum toxin types A, B, C.sub.1, D, E, F, G and mixtures thereof.

18. The method of claim 14, wherein the second amino acid sequence region of the polypeptide comprises an amine terminal of a toxin heavy chain derived from botulinum toxin type A.

19. The method of claim 14, wherein the third amino acid sequence region of the polypeptide comprises a toxin light chain derived from a neurotoxin selected from a group consisting of beratti toxin; butyricum toxin; tetani toxin; botulinum toxin types A, B, C.sub.1, D, E, F, G and mixtures thereof.

20. The method of claim 14, wherein the third amino acid sequence region of the polypeptide comprises a toxin light chain derived from botulinum toxin type A.

21. A method for improving patient function, the method comprising the step of peripheral administration of a botulinum toxin to a patient experiencing a non-muscle disorder related pain, thereby improving patient function as determined by improvement in one or more of the factors of reduced pain, reduced time spent in bed, improve hearing, increased ambulation, healthier attitude and a more varied lifestyle.

22. A method for treating post-operative pain, the method comprising the step of peripheral administration of an effective amount of a botulinum toxin before, during or immediately after a surgical procedure, thereby alleviating a post-operative pain, wherein the surgical procedure is not carried out to treat a muscle spasm.

23 A method for treating a visceral pain the method comprising the step of non-

systemic, local administration of an effective amount of a botulinum toxin, thereby alleviating a visceral pain.

24. A method for treating pain, the method comprising the step of peripheral administration of a neurotoxin to a mammal, wherein the pain is not substantially due to a muscle spasm.

25. The method of claim 24, wherein, the neurotoxin is a botulinum toxin.

26. The method of claim 24, wherein the pain is not secondary to a muscle spasm.

27. The method of claim 24, wherein the peripheral administration is by subcutaneous administration of the neurotoxin.

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L5: Entry 3 of 14

File: PGPB

Jan 29, 2004

PGPUB-DOCUMENT-NUMBER: 20040018212
PGPUB-FILING-TYPE: new
DOCUMENT-IDENTIFIER: US 20040018212 A1

TITLE: Joint pain treatment by peripheral administration of a neurotoxin

PUBLICATION-DATE: January 29, 2004

INVENTOR-INFORMATION:

| NAME | CITY | STATE | COUNTRY | RULE-47 |
|---------------------|---------------|-------|---------|---------|
| Aoki, Kei Roger | Coto de Caza | CA | US | |
| Cui, Minglei | Irvine | CA | US | |
| Jenkins, Stephen W. | Mission Viejo | CA | US | |

US-CL-CURRENT: 424/239.1

CLAIMS :

We claim:

1. A method for treating pain, the method comprising the step of peripheral administration of a neurotoxin to a mammal, wherein the pain treated is not associated with a muscle spasm.
2. The method of claim 1, wherein the neurotoxin comprises a neuronal binding moiety moiety which is substantially native to the neurotoxin.
3. The method of claim 1, wherein the neurotoxin is a botulinum toxin.
4. The method of claim 1, wherein the neurotoxin is a botulinum toxin elected from the group consisting of botulinum toxin types A, B, C.sub.1, D, E, F and G.
5. The method of claim 1, wherein the neurotoxin is botulinum toxin type A.
6. The method of claim 1, wherein the neurotoxin is a modified neurotoxin having at least one amino acid deleted, modified or replaced.
7. The method of claim 1, wherein the neurotoxin is made at least in part by a recombinant process.
8. The method of claim 1, wherein the neurotoxin is administered in an amount between about 0.01 U/kg and about 35 U/kg.
9. The method of claim 1, wherein the pain is substantially alleviated for between about 1 month and about 6 months.
10. The method of claim 1, wherein the peripheral administration step is carried out out prior to an onset of a nociceptive event or syndrome experienced by the mammal.

11. The method of claim 1, wherein the peripheral administration is carried out subsequent to an onset of a nociceptive event experienced by the mammal.
12. A method for alleviating pain, the method comprising the step of peripheral administration of a botulinum toxin to a human patient, thereby alleviating pain, wherein the pain is not associated with a muscle disorder.
13. The method of claim 12, wherein the neurotoxin is a botulinum toxin selected from the group consisting of botulinum toxin types A, B, C.sub.1, D, E, F and G.
14. A method for treating a pain, the method comprising the step of peripheral administration of a neurotoxin to a mammal, wherein the neurotoxin is a polypeptide comprising: a) a first amino acid sequence region comprising a wild type neuronal binding moiety, substantially completely derived from a neurotoxin selected from a group consisting botulinum toxin types A, B, C.sub.1, D, E, F, G and mixtures thereof; b) a second amino acid sequence region effective to translocate the polypeptide or a part thereof across an endosome membrane; and c) a third amino acid sequence region having therapeutic activity when released into a cytoplasm of a target cell, wherein the pain is not associated with a muscle spasm.
15. The method of claim 14, wherein the first amino acid sequence region of the polypeptide comprises a carboxyl terminal of a heavy chain derived from the neurotoxin.
16. The method of claim 14, wherein the neurotoxin is botulinum toxin type A.
17. The method of claim 14, wherein the second amino acid sequence region of the polypeptide comprises an amine terminal of a heavy chain derived from a neurotoxin selected from a group consisting of botulinum toxin types A, B, C.sub.1, D, E, F, G and mixtures thereof.
18. The method of claim 14, wherein the second amino acid sequence region of the polypeptide comprises an amine terminal of a toxin heavy chain derived from botulinum toxin type A.
19. The method of claim 14, wherein the third amino acid sequence region of the polypeptide comprises a toxin light chain derived from a neurotoxin selected from a group consisting of beratti toxin; butyricum toxin; tetani toxin; botulinum toxin types A, B, C.sub.1, D, E, F, G and mixtures thereof.
20. The method of claim 14, wherein the third amino acid sequence region of the polypeptide comprises a toxin light chain derived from botulinum toxin type A.
21. A method for improving patient function, the method comprising the step of peripheral administration of a botulinum toxin to a patient experiencing a non-muscle disorder related pain, thereby improving patient function as determined by improvement in one or more of the factors of reduced pain, reduced time spent in bed, improve hearing, increased ambulation, healthier attitude and a more varied lifestyle.
22. A method for treating post-operative pain, the method comprising the step of peripheral administration of an effective amount of a botulinum toxin before, during or immediately after a surgical procedure, thereby alleviating a post-operative pain, wherein the surgical procedure is not carried out to treat a muscle spasm.
23. A method for treating a visceral pain the method comprising the step of non-

24. A method for treating pain, the method comprising the step of peripheral administration of a neurotoxin to a mammal, wherein the pain is not substantially due to a muscle spasm.

26. The method of claim 24, wherein the pain is not secondary to a muscle spasm.

27. The method of claim 24, wherein the peripheral administration is by subcutaneous administration of the neurotoxin.

First Hit

File: PGPB

Mar 20, 2003

PGPUB-DOCUMENT-NUMBER: 20030054975
PGPUB-FILING-TYPE: new
DOCUMENT-IDENTIFIER: US 20030054975 A1

TITLE: Methods for treating fibromyalgia

PUBLICATION-DATE: March 20, 2003

INVENTOR - INFORMATION:

| NAME | CITY | STATE | COUNTRY | RULE-47 |
|-----------------|---------------------|-------|---------|---------|
| Voet, Martin A. | San Juan Capistrano | CA | US | |

US-CL-CURRENT: 514/2

CLAIMS:

What is claimed is:

1. A method for treating fibromyalgia, the method comprising the step of administering locally a therapeutically effective amount of a Clostridial neurotoxin to a peripheral location of a body of a patient afflicted with fibromyalgia, wherein the peripheral location is not a locus of pain, thereby treating fibromyalgia.
2. The method of claim 1 wherein the locus of pain and the peripheral location are located within a same dermatome.
3. The method of claim 1 wherein the peripheral location is in a head of the patient, and wherein the locus of pain is not in the head of the patient.
4. The method of claim 1 wherein the peripheral location is in a head of the patient, and wherein the locus of pain is at a fibromyalgia tender point.
5. The method of claim 1 wherein the peripheral location is in cranial area and/or a facial area of the patient, and wherein the locus of pain is at a fibromyalgia tender point.
6. The method of claim 1 wherein the neurotoxin is selected from the group consisting of botulinum neurotoxin types A, B, C, D, E, F, G, fragments thereof, derivatives thereof, mixtures thereof and combinations thereof.
7. The method of claim 1 wherein the neurotoxin is selected from the group consisting of botulinum neurotoxin types A, B, C, D, E, F and G.
8. The method of claim 1 wherein the Clostridial neurotoxin is a botulinum neurotoxin type A.
9. The method of claim 1 wherein the location of peripheral administration and the locus of pain have neuronal processes that are projected from the same spinal

sensory nerve root.

10. The method of claim 1 wherein the Clostridial neurotoxin is administered subcutaneously.

11. The method of claim 1 wherein the Clostridial neurotoxin is administered intramuscularly.

12. The method of claim 1 wherein the Clostridial neurotoxin is administered with a needle.

13. The method of claim 1 wherein the Clostridial neurotoxin is administered by needleless injection.

14. A method for treating pain, the method comprising the step of administering locally a therapeutically effective amount of a Clostridial neurotoxin to a peripheral location on a body of a patient, wherein the patient has a locus of pain, pain, and wherein the peripheral location is not at the locus of pain, thereby treating the pain.

15. The method of claim 14 wherein the locus of pain is at a fibromyalgia tender point.

16. The method of claim 15 wherein the patient has at least eleven loci of pain.

17. The method of claim 14 wherein the locus of pain and the peripheral location are located within a same dermatome.

18. The method of claim 14 wherein the neurotoxin is selected from the group consisting of botulinum neurotoxin types A, B, C, D, E, F, G, fragments thereof, derivatives thereof, mixtures thereof and combinations thereof.

19. The method of claim 14 wherein the neurotoxin is selected from the group consisting of botulinum neurotoxin types A, B, C, D, E, F and G.

20. The method of claim 14 wherein the Clostridial neurotoxin is a botulinum neurotoxin type A.

21. The method of claim 14 wherein the location of peripheral administration and the locus of pain have neuronal processes that are projected from the same spinal sensory nerve root.

22. The method of claim 14 wherein the Clostridial neurotoxin is administered subcutaneously.

23. The method of claim 14 wherein the Clostridial neurotoxin is administered intramuscularly.

24. The method of claim 14 wherein the Clostridial neurotoxin is administered with a needle.

25. The method of claim 14 wherein the Clostridial neurotoxin is administered by needleless injection.

26. A method for treating fibromyalgia, the method comprising the step of

the locus of pain have neuronal processes that are projected from the same spinal sensory nerve root.

43. The method of claim 35 wherein the Clostridial neurotoxin is administered subcutaneously.

44. The method of claim 35 wherein the Clostridial neurotoxin is administered intramuscularly.

45. The method of claim 35 wherein the Clostridial neurotoxin is administered with a needle.

46. The method of claim 35 wherein the Clostridial neurotoxin is administered by needleless injection.

47. A method for treating fibromyalgia, the method comprising the step of administering locally a therapeutically effective amount of a botulinum toxin type A to a dermatome of a patient afflicted with fibromyalgia, wherein the dermatome substantially encompasses a locus of pain which is at a fibromyalgia tender point, and wherein the local administration is not at the locus of pain, thereby treating fibromyalgia.

48. A method for treating pain, the method comprising the step of administering locally a therapeutically effective amount of a botulinum toxin type A to a dermatome of a patient, wherein the patient has a locus of pain which is at a fibromyalgia tender point, wherein the dermatome substantially encompasses the locus of pain, and wherein the local administration is not to the locus of pain, thereby treating the pain.

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CLAIMS:

We claim:

1. A method for treating pain, the method comprising the step of peripheral administration of a neurotoxin to a mammal, wherein the pain treated is not associated with a muscle spasm.
2. The method of claim 1, wherein the neurotoxin comprises a neuronal binding moiety moiety which is substantially native to the neurotoxin.
3. The method of claim 1, wherein the neurotoxin is a botulinum toxin.
4. The method of claim 1, wherein the neurotoxin is a botulinum toxin selected from the group consisting of botulinum toxin types A, B, C.sub.1, D, E, F and G.
5. The method of claim 1, wherein the neurotoxin is botulinum toxin type A.
6. The method of claim 1, wherein the neurotoxin is a modified neurotoxin having at least one amino acid deleted, modified or replaced.
7. The method of claim 1, wherein the neurotoxin is made at least in part by a recombinant process.
8. The method of claim 1, wherein the neurotoxin is administered in an amount between about 0.01 U/kg and about 35 U/kg.
9. The method of claim 1, wherein the pain is substantially alleviated for between about 1 month and about 6 months.
10. The method of claim 1, wherein the peripheral administration step is carried out out prior to an onset of a nociceptive event or syndrome experienced by the mammal.

systemic, local administration of an effective amount of a botulinum toxin, thereby alleviating a visceral pain.

24. A method for treating pain, the method comprising the step of peripheral
administration of a neurotoxin to a mammal, wherein the pain is not substantially due
due to a muscle spasm.

25. The method of claim 24, wherein, the neurotoxin is a botulinum toxin.

26. The method of claim 24, wherein the pain is not secondary to a muscle spasm.

27. The method of claim 24, wherein the peripheral administration is by subcutaneous administration of the neurotoxin.